

COLLECTIONS REALIZED AND OFFSET

Under PDUFA V, if cumulative collections for FY 2013 through FY 2015, plus an estimate of collections for FY 2016, exceed the fee revenue amounts specified in the appropriation acts for that period, FDA will be required to reduce the fee rates for FY 2017 by the cumulative amount that fees exceeded the amounts specified in appropriations during that period.

Table 5 depicts fee collections realized each fiscal year, collection amounts specified in the appropriations act, and offset amounts made when fees for FY 2007 and FY 2012 were set. No additional offsets are to be made under PDUFA V until FDA sets fees for FY 2017 in August 2016.

TABLE 5: PRESCRIPTION DRUG USER FEES COLLECTED, COLLECTION AMOUNTS SPECIFIED IN APPROPRIATIONS ACTS, AND OFFSET AMOUNTS AS OF SEPTEMBER 30, 2013

FISCAL YEAR	COLLECTIONS REALIZED	COLLECTION AMOUNT SPECIFIED IN APPROPRIATIONS ACT	AMOUNT IN EXCESS OF COLLECTION AMOUNT SPECIFIED IN APPROPRIATIONS ACT
1998	\$117,849,016	\$117,122,000	\$727,016
1999	\$125,729,367	\$132,273,000	-
2000	\$141,134,682	\$145,434,000	-
2001	\$138,421,429	\$149,273,000	-
2002	\$141,408,975	\$161,716,000	-
2003	\$218,302,684	\$222,900,000	-
2004	\$258,333,700	\$249,825,000	\$8,508,700
2005	\$287,178,231	\$284,394,000	\$2,784,231
2006	\$313,541,278	\$305,332,000	\$8,209,278
2007	\$370,560,934	\$352,200,000	\$18,360,934
Collections Exceeding Amounts Specified in Appropriations Acts through FY2007			\$38,590,159
Excess collections offset under 736(g)(4) when fees for FY 2007 were set			\$7,957,922
Excess collections offset under 736(g)(4) when fees for FY 2013 were set			\$30,974,959
2008	\$478,184,756	\$459,412,000	\$18,772,756
2009	\$531,874,297	\$510,665,000	\$21,209,297
2010	\$557,153,988	\$578,162,000	(\$21,008,012)
2011	\$593,264,939	\$667,057,000	(\$73,792,061)
2012	\$709,191,284	\$702,172,000	\$7,019,284
Collections FY 2008-2012 Compared to Amounts Specified in Appropriations Acts			(\$47,798,736)
2013	\$691,758,065	\$718,669,000	(\$26,910,935)
Net Balance to be Offset When Fees Are Set for FY 2017			\$0

As discussed on page 3, previous cohort year collections realized in FY 2013 have been updated from last year's report. The update reflects net collections for each cohort year through September 30, 2013. Cohort year fees collected subsequent to September 30, 2013, will be reported in the FY 2014 Financial Report. As Table 5 demonstrates, of the PDUFA V fee revenue collected to date, none of the fees collected are in excess of fee amounts specified in appropriations acts, and therefore no reserve for future collection offset is necessary at this time.